



Declaration of Conformity

Activated Charcoal Super Absorbent Dressing

This Declaration of Conformity is issued under the sole responsibility of Winner Medical Co., Ltd.

We hereby declare that the mentioned product/ attached list of products with CE marking comply with the applicable general safety and performance requirements and provisions of EU Medical Device Regulation (EU) 2017/745. And the CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Legal Manufacturer:	Winner Medical Co., Ltd. Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000005692
Authorized Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
SRN:	DE-AR-000000001
Product Name:	Refer to Appendix A and Appendix B
EMDN Code and Term Description:	Refer to Appendix A and Appendix B
Basic UDI-DI:	Refer to Appendix A and Appendix B
Intended Purpose:	Refer to Appendix A and Appendix B
Risk Classification:	Class IIb as per Rule 4 in Annex VIII of EU Medical Device Regulation (EU) 2017/745
Conformity Assessment Route:	Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIb Devices)
Applicable Standards:	EN ISO 13485:2016/A11: 2021 EN ISO 14971:2019/A11: 2021 EN ISO 20417: 2021 EN ISO 15223-1: 2021 EN ISO 10993-1: 2020 EN ISO 11135: 2014/A1:2019 EN ISO 10993-7: 2008/A1: 2022

	<p>EN ISO 11737-1: 2018</p> <p>EN ISO 11737-2:2020</p> <p>EN 13726-1: 2002</p> <p>EN 13726-2: 2002</p>
References to any CS:	Not Applicable
Identification of Notified Body:	<p>TÜV SÜD Product Service GmbH 0123</p> <p>Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY</p>
Identification of the Certificate(s):	<p>EU Quality Management System Certificate (MDR) No. G10 046241 0073 Rev. 02, issued by TÜV SÜD</p> <p>Valid from: 2025-06-24</p> <p>Valid until: 2028-07-09</p>
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p>Name: Amy Xu</p> <p>Signature: </p> <p>Senior Manager of Registration and Quality System</p> <p>Place of Issue: Shenzhen, China</p> <p>Date: 2025-06-24</p>



Appendix A: List of Product Range Covered under this Declaration of Conformity

General Device Group	Winner Product	EMDN Code	Risk Classification	Basic UDI-DI
Activated Charcoal Super Absorbent Dressing	Activated Charcoal Super Absorbent Dressing (Type I)	M04040902 (ACTIVATED CHARCOAL DRESSINGS, COMBINED WITH OTHER SUBSTANCES)	Class IIb Rule 4	694109403531EJ
	Activated Charcoal Super Absorbent Dressing (Type II)			

Intended purpose:

Activated Charcoal Super Absorbent Dressing (Type I and Type II) is an absorbent dressing for exudate management and reduction of malodour, it can be used on acute and hard-to-heal wounds producing all volumes and types of exudate, including high viscosity. Can be used on malodorous, infected and susceptible wounds. The contact site was dermal tissue and the contact time was less than 28 days.

Appendix B: List of Product names and Article codes Covered under this Declaration of Conformity

Winner Product	EMDN Code	Basic UDI-DI	B.Braun Code	Product description
Activated Charcoal Super Absorbent Dressing (Type I)	M04040902 (ACTIVATED CHARCOAL DRESSINGS, COMBINED WITH OTHER SUBSTANCES)	694109403531EJ	WIN9025006	Askina® Carbosorb 10 x 10 cm
			WIN9025014	Askina® Carbosorb 10 x 20 cm
			WIN9025015	Askina® Carbosorb 20 x 20 cm
			WIN9025007	Askina® Carbosorb 15 x 15 cm

Intended purpose:

Askina® Carbosorb is an absorbent dressing for exudate management and reduction of malodour, it can be used on acute and hard-to-heal wounds producing all volumes and types of exudate, including high viscosity. Can be used on malodorous, infected and susceptible wounds. The contact site was dermal tissue and the contact time was less than 28 days.

Revision History

Rev No.	Date	Comment	Author
A/0	2025-06-24	Initial Release of Technical Documentation under the Medical Device Regulation (EU) 2017/745	Lea Liu